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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,186	07/19/2001	Hideji Tajima	10287.46	9114
27683	7590	09/09/2005	EXAMINER	
HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202			CROSS, LATOYA I	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/909,186

Applicant(s)

TAJIMA, HIDEJI

Examiner

LaToya I. Cross

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-44 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-33 and 36-42 is/are rejected.
- 7) ☒ Claim(s) 34,35,43 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### DETAILED ACTION

This Office Action is in response to Applicants' After-Final amendments filed on June 14, 2005. Claims 11-44 are pending. Claims 11-14 are withdrawn from consideration as being directed to non-elected subject matter.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 15-19 is rejected under 35 U.S.C. 102(e) as being anticipated by US patent 6,649,404 to Vann et al.

Vann et al teach fibers having chemical species immobilized thereon (fiber array). The fibers may be coiled around one hub (1818) and then moved to another hub (1820) of a cassette – like device to allow for easier detection. See figures 18. The second hub (1820) may be considered a loop since the fiber array travels along the circular reel as it moves from the first hub. Each fiber array comprises a plurality of fibers having

chemical species immobilized thereon (col. 9, lines 49-62). The fiber construction may be a wire or optical fiber, which generally takes the shape of being slender and flexible (col. 10, lines 43-50). With respect to the chemical species being present on the fiber, Vann et al teach that different chemical species or multiple chemical species in different positions may be present. The preparation of each fiber is dependent on the type of fiber and the identity of the chemical species (col. 11, lines 34-43).

***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 15-33, 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,057,100 to Heynecker in view of US Patent 6,482,593 to Walt et al.

Heynecker discloses oligonucleotide arrays. The oligonucleotide arrays are fibers, which comprise a support having oligonucleotides attached thereto.

Oligonucleotides are substances for detection of analytes in a sample. The fiber support is a base member to which the oligonucleotides are attached and is disclosed as being made from materials such as polyethylene (col. 3, lines 16-35). At col. 4, lines 14-15, Heynecker teaches that the fiber is "flexible". The arrays have at least two different oligonucleotides attached, preferably more than two (col. 4, lines 17-22). Heynecker

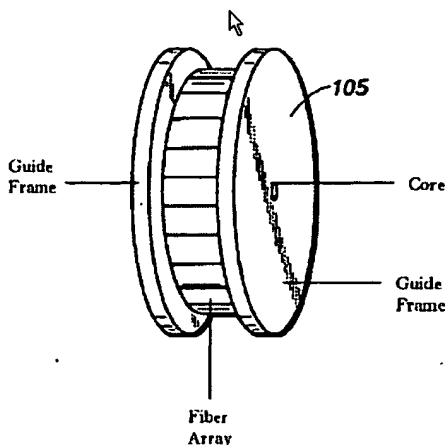
further discloses that each oligonucleotide species is arranged in distinct linear rows (side by side) to form an immobilized oligonucleotide strip, i.e. an unrolled configuration (col. 4, lines 47-56). With respect to the rolled configuration, Heynecker discloses fibers being spiraled around a center core, as shown in figure 3D. Further, Heynecker discloses "spacer fibers" to aid in alignment. With respect to the tubular member, Heynecker discloses a casing (105), which houses the fibers that are coiled around the core member. Heynecker discloses that the disks may be rotated through a solution of test sample (col. 6, lines 28-37). The reference also discloses using fluorescent labels to detect the target sequences, wherein a laser source can be used for detection. It would have been obvious to one of ordinary skill in the art to provide the test solution in a container (tubular member) and that the tubular member would have a means to put solution into the container and take solution out of the container. Such would have been obvious because the user would have needed to place the test solution into the container and when the test solution needs to be changed or discarded, the test solution would need to be removed from the container.

Heynecker differs from the instantly claimed invention in that there is no disclosure of oligonucleotides are in a fixed location on the fiber, wherein the location corresponds with a particular chemical structure.

Walt et al teach biosensors for detecting oligonucleotide species in a fluid sample. The biosensors of Walt et al comprise an optical fiber (12) having oligonucleotides attached to the fiber strand (col. 13, lines 24-31). At col. 14, lines 62-64 and col. 15, lines 28-41, Walt et al teach that each oligonucleotide deposit on the fiber serves as one fixed probe immobilized at a predetermined spatial position. Further, Walt et al teach an identifying label, such as a dye, on the fiber to reflect the presence of a target species (col. 18, line 60 – col. 19, line 11).

It would have been obvious to one of ordinary skill in the art to have the oligonucleotides of Heynecker to be attached to the fiber at predetermined locations to allow detection at a particular location to determine the presence of a particular analyte in the sample. Where the oligonucleotides are positioned at specific locations on the fiber, the user need only observe the presence of a reaction at that location to determine the presence of a particular analyte in the sample.

Also, Heynecker does not explicitly teach that the casing (105) is made of permeable material. However, such would have been obvious to one of ordinary skill in the art because the casing will be rotated through a sample solution. Thus, if the casing were made of permeable material, then it can be assured that the sample solution reaches the reaction sites on the fibers, providing for accurate detection. Below is a description of figure 3E of Heynecker.



#### *Allowable Subject Matter*

4. Claims 34-35 and 43-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### *Response to Arguments*

5. Applicant's arguments filed February 14, 2005 (and entered into the record on June 15, 2005) have been fully considered but they are not persuasive. In response to the obviousness rejection over Heynecker in view of Walt, Applicants argue that neither reference teaches a single base member that is spiraled around cylindrical structure. The Examiner would like to point out that none of the claims require a "single" base member. The claims merely recite a base member to which detection substances are

fixed. The fiber arrays (group of fibers) having oligonucleotides attached thereto, as taught by Heynecker, are sufficient to meet the claimed limitation. Furthermore, only claim 29 recites the limitation that the base member is spiraled around a core. Thus, this argument only applies to claim 29. The Examiner does not consider this to be a persuasive argument, with respect to claim 29, because Heynecker teaches a core member (95) shown in Figure 3C that may have the base members coiled around the core, as shown in Figure 3D. Applicants' argument that Figure 3D shows four different arrays is immaterial, since a single base member is not recited in the claims.

With respect to claim 25 and the tubular member, Applicants argue that there is no teaching or suggestion of a means for drawing liquid into and out of the tubular member. In response, the Examiner notes that Heynecker teaches that the disks may be rotated through a test solution. The tubular member could be considered to be the container in which the test solution is contained. It would have been obvious to one of ordinary skill in the art that the test solution would have to be put into and drawn out of the container by some means, although the particular means is not specifically disclosed.

With respect to the combination of teachings from Heynecker and Walt, Applicants argue that there is no motivation to combine the references. The Examiner disagrees because Walt clearly provides a means by which analytes in a sample may be



detected by observing reactions at particular spatial locations on the fiber. Detection by observing spatial locations is a conventional and well-known process for determining the presence of analytes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER